K100593

1 of 1

5. Premarket Notification [510(k)] Summary

Submitted By: LSI SOLUTIONS®, Inc.
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Contact: Jude S. Sauer, M.D., President and CEO, or
Peter Spath, Regulatory Director

OCT 13 2010

Date Prepared: February 22, 2010

Common Name: Needle Guide

Trade Name: LSI SOLUTIONS® Suture Placement Devices and Accessories

Classification Name:

Manual Surgical Instrument for General Use	21CFR Part 878.4800
Non-absorbable Surgical Sutures	21CFR Part 878.5000
Non-absorbable Surgical Sutures	21CFR Part 878.5010

Predicate Devices:

LSI Suture Placement Device and Accessories	(K981531)
LSI Flexible Suture Placement Device and Accessories	(K011016)
LSI "R" Series Placement Device and Accessories	(K040232)
LSI Suture Quick Load® Products	(K031443)
Coalescent Surgical U-Clip®	(K012317)

Description: LSI SOLUTIONS® Suture Placement Devices, Accessories and Quick Load® products, specifically the RD-180 suturing device and its 2-0 non-absorbable polyester and polypropylene suture load units along with the TK Ti-Knot® knot replacement device and its Titanium Knot® loads, will effectively approximate tissue and prosthetic material.

Intended Use: These LSI SOLUTIONS® suture placement products are intended for use in the approximation of soft tissue and prosthetic materials.

Test Data: A "Prosthetic Fixation Study" employed an *ex-vivo* porcine tissue model to compare LSI cleared suturing products to a Coalescent U-Clip® predicate device and USP standards. Multiple tests were performed covering a variety of different prosthetic material types. All data fell within internal specification requirements, as well as external standard requirements and device performance expectations.

Summary: Included in this submission are the same devices cleared in previous LSI SOLUTIONS® 510(k) submissions for the approximation of soft tissue. Based on the comparison of the Coalescent U-Clip®, analysis of the historic and recently developed data and our ongoing success with the same already cleared products, we believe they are substantially equivalent for the approximation of soft tissue and prosthetic materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LSI Solutions, Inc.
% Mr. Peter Spath
Regulatory Director
7796 Victor-Mendon Road
Victor, New York 14564

OCT 1 3 2010

Re: K100593
Trade/Device Name: LSI SOLUTIONS®, Inc. Suture Placement Devices and Accessories
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW, GAS, HCF, GCJ
Dated: September 24, 2010
Received: September 29, 2010

Dear Mr. Spath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

K100593

OCT 13 2010

510(k) Number (if known): K100593

Device Name: LSI SOLUTIONS®, Inc. Suture Placement Devices and Accessories

Indications for Use: Approximation of soft tissue and prosthetic materials

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices